

**K021373 H12+HOLTER RECORDER**Jun 27, 2002  
57 days to decisionK021373 · Product code: **MWJ** · CardiovascularSource: <https://www.510kdatabase.net/k021373/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrocardiograph, Ambulatory (without Analysis) (MWJ)
Date received	May 1, 2002
Decision date	Jun 27, 2002
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mortara Instrument, Inc.</b>
Location	Walker, MI, US
Contact	HARLAN L VAN MATRE
510(k) history	51 submissions · 51 cleared · 1983-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k021373/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 19, 2026